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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,649	06/04/2002	Pierre Belhumeur	1051-1-019	6750
7590 04/24/2006				
Klauber & Jackson 411 Hackensack Avenue Hackensack, NJ 07601		EXAMINER BARNHART, LORA ELIZABETH		
		ART UNIT 1651		
DATE MAILED: 04/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/980,649	BELHUMEUR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant should note that the examiner for the case has changed.

Claims 1-13 are pending.

### ***Election/Restrictions***

Applicant's election with traverse of various species in the reply filed on 2/13/06 is acknowledged. Upon inspection of the claims and specification, however, the new examiner has determined that a replacement restriction is necessary. The following requirement for restriction and election of species should be substituted for the requirement mailed 6/21/05. Any inconvenience is regretted.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Prion protein degradation indicators: (a) Sup35p, (b) Ure2p, and (c) Het-s protein, as in claim 5, for example.

Determination methods: (d) determining the weight or the mass, (e) quantifying radicals, (f) colorimetric variations, (g) radiometry, (h) nephelometry, (i) immuno-enzymatic method, (j) western blotting, (k) dot blotting, (l) radioimmunoassay, (m) circular dichroism, (n) electron microscopy, (o) fluorescent microscopy, (p) FT-IR spectroscopy, (q) Congo red binding, and (r) proteinase digestion, as in claim 8, for example.

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Sterilization processes: (s) autoclaving, (t) chemical exposure, (u) dry heating, (v) low temperature plasma gas, (w) ozone-based exposure, (x) sterilization techniques using alkylant sterilizing agents, and (y) sterilization techniques using oxidizing sterilizing agents, as in claim 9, for example.

Chemical exposure reagents: (z) detergent, (a') ethylene oxide, (b') protease, (c') sodium hydroxide, and (d') enzyme, as in claim 10, for example.

Container materials: (e') paper, (f') glass, (g') borosilicate, (h') metal, (i') polymer, (j') alloy, and (k') composite, as in claim 12, for example.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, applicant should elect ONE prion protein degradation indicator from (a)-(c) above, ONE determination method from (d)-(r) above, ONE sterilization process from (s)-(y) above, and ONE container material from (e')-(k') above. If species (t) is elected, applicant should also elect ONE chemical exposure reagent from (z)-(d') above. Claims 2-6 will be examined to the extent that they read on the elected prion protein degradation inhibitor; that is, if species (a) is elected, claim 3 will be interpreted as being limited to *Saccharomyces cerevisiae*, and claim 4 will be interpreted as being limited to the SUP35 gene. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

**Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form**

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**or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.** The examiner points out that a requirement for an election of species is for search purposes only and does not necessarily narrow the scope of patentable claims, since all nonelected species may be rejoined at the time of allowance. See 37 C.F.R. §1.146 for a discussion of species election practice. In short, electing one species does not preclude consideration of the nonelected species later in the prosecution, *i.e.* at the time of allowance. The fact that all of the claims are generic is precisely the reason for the requirement for species election; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Each of claims 1-13 is generic to at least one of the groups of species recited above.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents. Specifically, prion protein degradation indicators (a)-(c) are distinct proteins that are produced by distinct organisms. Determination methods (d)-(r) are not equally applicable to all quantifications. Sterilization processes (s)-(y) are

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not equally applicable to all surfaces or samples, as is the case for chemical exposure reagents (z)-(d'). Container materials (e')-(k') would not all be useful for holding the same types of samples. Therefore, each of these groups lacks inventive unity among each and every species within the group.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Lora E. Barnhart**, whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

leb

SANDRA E. SAUCIER  
PRIMARY EXAMINER

